GEDEON RICHTER

CERTIFICATE OF COMPLIANCE

Name of the product:	**Drovelis**
Dosage form:	film-coated tablet
Strength/potency:	Estetrol 14.2 mg/ Drospirenone 3 mg and placebo
Package size and type:	1x24+4/blister
Batch number:	**Z41327A**
Manufacturing date:	01 2024
Expiry date:	01 2028
Quantity of finish product	6 696 boxes
Importing country:	**Ukraine**
Marketing authorization number:	UA/20281/01/01
Name of the MAH:	Gedeon Richter Plc.
Address:	Gyömrői út 19-21., Budapest, 1103, Hungary
Name of the bulk	Drospirenone 3 mg/ Estetrol 14.2 mg film-coated tablet
Batch number	**T42119**
Manufacturing site	Gedeon Richter Plc.
Address:	Gyömrői út 19-21., Budapest, 1103, Hungary
Authorisation number:	HU-M-RICH
Certificate of GMP compliance:	OGYÉI/20786-7/2022
Name of the bulk	Placebo film-coated tablets
Batch number	**T41613**
Manufacturing site	Gedeon Richter Plc.
Address:	Gyömrői út 19-21., Budapest, 1103, Hungary
Authorisation number:	HU-M-RICH
Certificate of GMP compliance:	OGYÉI/20786-7/2022
Packaging site	Gedeon Richter Plc.
Address:	Gyömrői út 19-21., Budapest, 1103, Hungary
Authorisation number:	HU-M-RICH
Certificate of GMP compliance:	OGYÉI/20786-7/2022
Release site	Gedeon Richter Plc
Address	Gyömrői út 19-21., Budapest, 1103, Hungary
Authorisation number:	HU-M-RICH
Certificate of GMP compliance:	OGYÉI/20786-7/2022
I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including bulk packaging and quality control at the above-mentioned site(s) in full compliance with the GMP requirements of the European Union and the Quality Agreement. The batch processing, bulk packaging and analysis records have been reviewed and found to be in compliance with GMP.	
Results of analysis:	CoA
Remarks:	
Released by: [redacted]	

Date of release: 04.04.2024
Date of issue: 04.04.2024

Tünde Kun
Qualified Person

Вх [illegible] № 0044 [illegible]

GEDEON RICHTER

CERTIFICATE OF ANALYSIS

Name of the product:	**Drovelis® 3 mg/14.2 mg**	
Dosage form:	film-coated tablets	
Strength/potency:	Drospirenone 3 mg/ Estetrol 14.2 mg/ placebo	
Batch number:	Z41327A	
Manufacturing date:	01 2024	
Expiry date:	01 2028	
TESTS	**ACCEPTANCE CRITERIA**	**RESULTS**
CHARACTERS		
	Pink, round, biconvex film-coated tablet, with ◎ (drop)-shaped engraving on one side.	conforms
AVERAGE MASS		
	0.0790 -0.0870 g	0.0806 g
IDENTIFICATIONS		
Estetrol and drospirenone	Identical, tested with HPLC in house method Identical, tested with DAD in house method	conforms conforms
RELATED SUBSTANCES		
	6-oxo-estetrol not more than 0.5% 9,11-didehydro-estetrol not more than 0.5% 3-hydroxy-15,16-dioxo-estratriene not more than 0.5% any other individual degradation product of estetrol origin not more than 0.2% total degradation products of estetrol origin not more than 2.0% 17-epi-drospirenone (Ph. Eur. Impurity E) not more than 1.0% any other individual degradation product of drospirenone origin not more than 0.5% total degradation products of drospirenone origin not more than 1.0 %	<0.03% <0.05% <0.03% <0.05% <0.05% <0.03% <0.03% <0.03%
MICROBIOLOGICAL PURITY		
(periodic test)	Total acrobic microbial count (TAMC): not more than 1000 CFU/g Total yeasts and moulds count (TYMC): not more than 100 CFU/g Absence of Escherichia coli (1 g)	<10 CFU/g <10 CFU/g conforms
ASSAY		
Estetrol	14.20 mg / film-coated tablet (13.49 - 14.91 mg) 95.0 - 105.0 %	14.10 mg/ftbl. 99.3%
Drospirenone	3.000 mg / film-coated tablet (2.850 - 3.150 mg) 95.0 - 105.0 %	2.980 mg/ftbl. 99.3%

Chemical Works of Gedeon Richter Plc.
Headquarters: H-1103 Budapest, Gyömrői út 19-21., Hungary • Postal address: H-1475 Budapest 10., Pf. 27., Hungary • Phone: +36 1 431 4000
www.gedeonrichter.com
Notification of comments on this certificate can be sent to: **certificate_complaint@richter.hu**

GEDEON RICHTER

CERTIFICATE OF ANALYSIS

Name of the product:	**Drovelis® 3 mg/14.2 mg**	
Dosage form:	film-coated tablets	
Strength/potency:	Drospirenone 3 mg/ Estetrol 14.2 mg/ placebo	
Batch number:	Z41327A	
Manufacturing date:	01 2024	
Expiry date:	01 2028	
TESTS	**ACCEPTANCE CRITERIA**	**RESULTS**
DISSOLUTION		
Estetrol	Not less than 80 % (Q) of the active substance dissolves in 15 minutes.	94%
Drospirenone	Not less than 80 % (Q) of the active substance dissolves in 30 minutes.	102%
UNIFORMITY OF DOSAGE UNITS		
Active substance -Content uniformity (CU)	Acceptance value (AV) < L1 (n = 10) or Acceptance value (AV) < L1 (n = 30), and in this case minimum > (1 – L2 x 0.01)M, maximum < (1 + L2 x 0.01)M, where L1 = 15.0, L2 = 25.0 Estetrol Drospirenone	 AV= 5.0 AV= 4.9
The quality of the product conforms to the specification: No. 5-01667-Q1-01-01		
2/3		

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GEDEON RICHTER

CERTIFICATE OF ANALYSIS

Name of the product:	**Drovelis® 3 mg/14.2 mg**	
Dosage form:	film-coated tablets	
Strength/potency:	Drospirenone 3 mg/ Estetrol 14.2 mg/ placebo	
Batch number:	Z41327A	
Manufacturing date:	01 2024	
Expiry date:	01 2028	
	Placebo film-coated tablets	
TESTS	**ACCEPTANCE CRITERIA**	**RESULTS**
CHARACTERS		
	White to off-white round, biconvex film-coated tablet, with ◎ (drop)-shaped engraving on one side.	conforms
AVERAGE MASS		
	0.0790 - 0.0870 g	0.0830 g
IDENTIFICATION		
Absence of active substance estetrol monohydrate	It is not tested, release can be performed based on the documentation of weighing. If necessary, the absence of active substances can be proved by the referred analytical method.	
Absence of active substance drospirenone	It is not tested, release can be performed based on the documentation of weighing. If necessary, the absence of active substances can be proved by the referred analytical method.	
MICROBIOLOGICAL PURITY		
(periodic test)	Total aerobic microbial count (TAMC): not more than 1000 CFU/g	<10 CFU/g
	Total yeasts and moulds count (TYMC): not more than 100 CFU/g	<10 CFU/g
	Absence of Escherichia coli (1 g)	conforms
DISINTEGRATION		
	not more than 15 min	2 min.
The quality of the product conforms to the specification: No. 5-01668-Q1-01-01		
3/3		

Date: 04.04.2024

Approved by

Tünde Kun
Qualified Person